

Medical application instruction for POLYOXIDONIUM[®]

Registration number: P N002935/04

Trade name: Polyoxidonium[®]

International Nonproprietary Name: Azoximer bromide

Chemical name: copolymer of N-oxide 1,4-ethylene piperazine and (N- carboxymethyl)-1,4-ethylene piperazinium bromide

Drug form: tablets

Composition in one tablet:

Active substance: Azoximer bromide 12 mg;

Excipients: mannitol 3.6 mg, povidone K17 2.4 mg, lactose monohydrate 185.0 mg, potato starch 45.0 mg, stearic acid 2.0 mg.

Description: Round white or white with yellowish tint flat faced beveled one side scored tablets with the other side lettering «PO».

Pharmacological group: immune modulator

ATC Code: [L03]

PHARMACOLOGICAL PROPERTIES

Polyoxidonium[®] tablets possesses an immune modulating action, increases the organism resistance to local and general infections. Polyoxidonium' main mechanism of action is the direct effect on the phagocytic cells and natural killers together with antibody production stimulation.

Polyoxidonium[®] activates the peripheral blood phagocytes and tissue macrophages action promoting more intensive infection elimination from the organism from the nidus of infection. Besides, Polyoxidonium[®] stimulates regional lymph nodes lymphoid cells, namely B-cells to produce secretory IgA.

When sublingually applied Polyoxidonium[®] activates the lymphoid cells of nasal cavity, Eustachian tubes, oropharynx, bronchi. Additionally Polyoxidonium[®] intensifies saliva bactericidal properties.

Being orally administered Polyoxidonium[®] activates intestine lymph nodes lymphoid cells as well. As a result of Polyoxidonium complex action the ENT, respiratory and gastrointestinal tract resistance to infection develops.

Together with the immune modulating properties Polyoxidonium[®] possesses an expressed detoxicating and antioxidant properties; is able to eliminate toxins, heavy metals ions from the organism, and inhibits the lipid peroxidation. All properties mentioned are determined by Polyoxidonium structure and high molecular nature.

Polyoxidonium application for secondary immune deficiencies allows to increase therapy efficacy and shorten its duration, significantly to reduce the antibiotics, broncholytics, glucocorticoids application, and to lengthen the remission period.

The preparation is well tolerated, has no mitogenic, polyclonal activity, free from antigen properties, and has no allergenic, mutagenic, embryo toxic, teratogenic and cancerogenic potential.

PHARMACOKINETICS

Polyoxidonium tablets 12 mg when orally administered quickly absorbed from gastrointestinal tract; its bioavailability is nearly 50%. Polyoxidonium maximal blood plasma concentration is registered three hours after the application. Polyoxidonium[®] pharmacokinetics is linear function (plasma concentration is proportional to preparation dose administered).

Polyoxidonium is hydrophilic compound: apparent distribution volume is about 0.5 l/kg reflecting the preparation distribution essentially in extracellular fluid. Polyoxidonium semi-absorption period is 35 minutes, elimination period is 18 hours. Polyoxidonium degrades to oligomers that are excreted mainly by kidney. No preparation accumulation was detected.

INDICATIONS

Polyoxidonium[®] tablets is approved in adults and adolescents over 12 years old for the treatment and prophylaxis of the infection (viral, bacterial and fungal etiology) inflammatory diseases resistant to conventional therapy. Polyoxidonium[®] can be applied both in exacerbation state and in remission period.

For complex therapy:

- acute and chronic recurrent infection inflammatory diseases of oropharynx, nasal sinus, upper respiratory tract, inner and middle ear;
- allergic diseases complicated with recurrent bacterial, fungal or viral infection (including pollinosis, bronchial asthma);
- sickly individuals rehabilitation;

As monotherapy:

- recurrent herpetic infection prophylaxis;
- seasonal prophylaxis for chronic infection exacerbation of oropharynx, nasal sinus, upper respiratory tract, inner and middle ear; influenza and ARI prophylaxis in pre-epidemic period;
- influenza and other ARI prophylaxis in immunocompromized patients;
- correction of secondary immune deficiencies due to aging or negative factors influence.

CONTRAINDICATIONS

Individual hypersensitivity to the preparation. Children under 12 years old.

PRECAUTIONS

Acute kidney insufficiency, lactose intolerance, lactase insufficiency, glucogalactose malsorbtion.

PREGNANCY AND LACTATION

Polyoxidonium[®] is contraindicated for pregnant and breast-feeding women (no application experience). No data concerning the Polyoxidonium[®] excretion into the breast milk are available.

POSOLOGY AND ADMINISTRATION WAY

Polyoxidonium[®] tablets 12 mg is administered orally and sublingually 20-30 minutes prior the meat, 1, 2 or three times a day. The administration way and daily dose is determined by physician based on diagnosis, disease acuity and severity.

THE WAYS OF SOME RECOMMENDED APPLICATION SCHEDULES AS A COMPLEX THERAPY:

Sublingually:

- Infection (bacterial, viral, fungal) processes in oropharynx: one tablet twice a day with 12-hour interval for 10-14 days. Acute severe herpetic and fungal oral cavity infection: 1 tablet three times a day with 8-hour intervals for 15 days.
- Nasal sinus chronic diseases and chronic otitis: 1 tablet twice a day with 12-hours interval for 5-10 days.
- Chronic tonsillitis: 1 tablet 3 times a day with 8-hour intervals for 10-15 days.
- Upper respiratory tract diseases: for adults 2 tablets twice a day, for adolescents 1 tablet 12 mg twice a day with 12-hour interval for 10-14 days.
- Influenza and ARIs prophylaxis: for immunocompromised falling ill more than 4 times a year, during the pre-epidemiological season: for adults 2 tablets, for adolescents 1 tablet twice a day with 12-hours interval for 10-14 days.

Orally:

- Upper respiratory tract chronic infections: for adults 2 tablets twice a day with 12-hour interval, for adolescents 1 tablet twice a day with 12-hours interval for 10-14 days.

SIDE EFFECTS

None

OVERDOSE

Not described.

INTERACTION WITH OTHER DRUG PREPARATIONS

No interaction with other drug preparation described. Polyoxidonium[®] can be applied with many of drugs, including antibiotics, antivirals, antifungal and antihistamine preparations, broncholytics, glucocorticoids, cytostatics and β -adrenomimetics.

SPECIAL WARNINGS

No one should exceed the doses recommended and treatment course duration without the physician advice.

Polyoxidonium[®] does not influence on the ability to drive and operate with machines.

PHARMACEUTICAL FORM

Tablets containing 12 mg of Polyoxidonium[®], 10 units in PVC/Alum blisters in cardboard box together with application instruction, one or two package in the pack.

STORAGE CONDITIONS

Store at 2-25°C.

Keep out of reach of children.

SHELF LIFE

Two years. Do not apply the preparation after the indicated shelf life completion. Shelf life is printed on the package.

LEGAL CLASSIFICATION

Without prescription.

MANUFACTURER

LLC "NPO Petrovax Pharm"

Legal address/ Address for consumers' reclamations:

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